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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/563,818

01/06/2006

Koji Suematsu

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22850

7590

08/20/2009

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EXAMINER

STRZELECKA, TERESA E

ART UNIT

PAPER NUMBER

1637

NOTIFICATION DATE

DELIVERY MODE

08/20/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/563,818	<b>Applicant(s)</b> SUEMATSU ET AL.	
	<b>Examiner</b> TERESA E. STRZELECKA	<b>Art Unit</b> 1637	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 June 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 23,25-28,30 and 32-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23,25-28,30 and 32-37 is/are rejected.
- 7) ☒ Claim(s) 33 and 35-37 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on June 26, 2009 has been entered.

2. Claims 23-37 were previously pending, with claims 24, 28 and 32-37 withdrawn from consideration. Applicants amended claims 23, 28, 30 and 33-37 and cancelled claims 24, 29 and 31. Claims 23, 25-28, 30 and 32-37 will be examined.

3. Applicants' cancellation of claims 29 and 31 overcame all the previously presented objections and rejections for these claims, the rejection of claims 23, 25-27 and 29-31 under 35 U.S.C. 112, first paragraph, enablement and the rejection of claims 23, 25-27, 29 and 30 under 35 U.S.C. 112, second paragraph. All other previously presented rejections are maintained as discussed in the "Response to Arguments" section below.

4. Applicants' evidence submitted June 26, 2009 is ineffective to overcome the remaining rejections for reasons discussed below.

### ***Response to Arguments***

5. Applicant's arguments filed June 26, 2009 have been fully considered but they are not persuasive.

Regarding incorporation by reference and rejection of claims 23, 25-27, 29 and 30 under 35 U.S.C. 112, first paragraph (new matter and written description), Applicants argue that the version of sequence with GenBank Accession No. AL162497 has been unambiguously identified and is

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contained in SEQ ID NO: 18 and therefore the positions of the polymorphisms are also unambiguously defined.

Whereas this is correct, the specification has not been amended to reflect this fact. Applicants amended the specification to identify the version of sequence with GenBank Accession No. AL162497, but no language has been inserted indicating that this version is incorporated by reference as SEQ ID NO: 18. Further, Applicants did not identify the version of accession No. XM\_007095 or provide a sequence for it. The specification identified the positions of the polymorphisms with respect to the first ATG codon of the sequence with accession No. XM\_007095. The amended claims refer to the position of the polymorphisms within SEQ ID NO: 18, which is much larger than the gene itself. Therefore, to arrive at these positions, one had to first determine the position of the first ATG codon of the sequence with accession No. XM\_007095 (which position was not provided by Applicants at the time of filing) and then translate this position by aligning the sequence with accession No. XM\_007095 with SEQ ID NO: 18. However, given the fact that there were six versions of the sequence with accession No. XM\_007095 and the position of the ATG codon within the sequence with accession No. XM\_007095 was not identified in the original disclosure, the polymorphism positions are not unambiguously identified.

### ***Incorporation by Reference***

6. The attempt to incorporate subject matter into this application by reference to the GenBank Accession numbers on page 13 and 14 is ineffective because:

- a) there is no statement that these accession numbers were incorporated by reference,
- b) the versions of sequence with accession No. XM\_007095 that were used were not identified.

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The amendment to add inadvertently omitted material pursuant to 37 CFR 1.57(a) filed June 26, 2009 is not in compliance with 37 CFR 1.57(a) because: Applicants amended the specification to indicate that the version of the GenBank Accession No. AL162497 was 20. However, there is no language indicating incorporation by reference of this sequence or the fact that the incorporated sequence has SEQ ID NO: 18. Further, Applicants did not indicate which version of the sequence with accession No. XM\_007095 was used by Applicants, or that this sequence is incorporated by reference. No SEQ ID NO was provided for the gene sequence.

The incorporation by reference will not be effective until correction is made to comply with 37 CFR 1.57(b), (c), or (d). If the incorporated material is relied upon to meet any outstanding objection, rejection, or other requirement imposed by the Office, the correction must be made within any time period set by the Office for responding to the objection, rejection, or other requirement for the incorporation to be effective. Compliance will not be held in abeyance with respect to responding to the objection, rejection, or other requirement for the incorporation to be effective. In no case may the correction be made later than the close of prosecution as defined in 37 CFR 1.114(b), or abandonment of the application, whichever occurs earlier.

Any correction inserting material by amendment that was previously incorporated by reference must be accompanied by a statement that the material being inserted is the material incorporated by reference and the amendment contains no new matter. 37 CFR 1.57(f).

### ***Claim Objections***

7. Claims 33 and 35 are objected to because of the following informalities: the period at the end of the claim is missing. Appropriate correction is required.

8. Claims 33, 35 and 36 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to

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cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

A) Claim 33 depends from claim 32, which in turn depends from claim 23. Since claim 23 already contains a limitation of assessing the risk of vesnarinone-induced granulocytopenia, claim 33 is not further limiting.

B) Claim 35 depends from claim 34, which in turn depends from claim 23. Since claim 23 already contains a limitation of assessing the risk of vesnarinone-induced granulocytopenia, claim 35 is not further limiting.

C) Claim 36 depends from claim 32, which in turn depends from claim 23. Since claim 23 already contains a limitation of assessing the risk of vesnarinone-induced granulocytopenia, claim 36 is not further limiting.

### ***Double Patenting***

9. Claims 33, 35 and 36 are objected to under 37 CFR 1.75 as being a substantial duplicates of claims 32, 34 and 32, respectively. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

A) Claim 33 depends from claim 32, which in turn depends from claim 23. Since claim 23 already contains a limitation of assessing the risk of vesnarinone-induced granulocytopenia, claim 33 does not further limit claim 32, and therefore it is a substantial duplicate of claim 32.

B) Claim 35 depends from claim 34, which in turn depends from claim 23. Since claim 23 already contains a limitation of assessing the risk of vesnarinone-induced granulocytopenia, claim 35 does not further limit claim 34, and therefore it is a substantial duplicate of claim 34.

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C) Claim 36 depends from claim 32, which in turn depends from claim 23. Since claim 23 already contains a limitation of assessing the risk of vesnarinone-induced granulocytopenia, claim 36 does not further limit claim 32, and therefore it is a substantial duplicate of claim 32.

***Claim Rejections - 35 USC § 112, new matter***

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 23, 25-28, 30 and 32-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are rejected for the following reasons. The specification as originally filed did not provide a sequence listing or a description of where the polymorphisms in the IRS-2 gene are located. Specifically, Applicants state on page 13 and 14, paragraphs [0038]-[0039], that the IRS2 gene is included in the sequence with GenBank Accession No. AL162497, and the gene itself has accession No. XM\_007095, and corresponds to bp 93,673-126,402 of the GenBank Accession No. AL162497. Applicants designated the positions of the polymorphic bases as follows (page 14, the end of the first paragraph):

“The position numbers of SNPs as described in the specification or the figure correspond to the position numbers counting from A of ATG that is used as a codon for Met at N-terminus of protein when mRNA is translated into protein (translation initiation codon).” Applicants did not indicate which bp of the XM\_007095 is considered to be the A of the ATG codon.

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Applicants did not incorporate the two accession numbers by reference in the originally filed specification. Applicants amended the specification to identify the version of sequence with GenBank Accession No. AL162497, but no language has been inserted indicating that this version is incorporated by reference as SEQ ID NO: 18. Further, Applicants did not identify the version of accession No. XM\_007095 or provide a sequence for it. The specification identified the positions of the polymorphisms with respect to the first ATG codon of the sequence with accession No. XM\_007095. The amended claims refer to the position of the polymorphisms within SEQ ID NO: 18, which is much larger than the gene itself. Therefore, to arrive at these positions, one had to first determine the position of the first ATG codon of the sequence with accession No. XM\_007095 (which position was not provided by Applicants at the time of filing) and then translate this position by aligning the sequence with accession No. XM\_007095 with SEQ ID NO: 18. However, given the fact that there were six versions of the sequence with accession No. XM\_007095 and the position of the ATG codon within the sequence with accession No. XM\_007095 was not identified in the original disclosure, the polymorphism positions are not unambiguously identified.

Therefore the claims contain new matter.

***Claim Rejections - 35 USC § 112, written description***

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 23, 25-28, 30 and 32-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the



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relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification as originally filed did not provide a sequence listing or a description of where the polymorphisms in the IRS-2 gene are located. Specifically, Applicants state on page 13 and 14, paragraphs [0038]-[0039], that the IRS2 gene is included in the sequence with GenBank Accession No. AL162497, and the gene itself has accession No. XM\_007095, and corresponds to bp 93,673-126,402 of the GenBank Accession No. AL162497. Applicants designated the positions of the polymorphic bases as follows (page 14, the end of the first paragraph):

“The position numbers of SNPs as described in the specification or the figure correspond to the position numbers counting from A of ATG that is used as a codon for Met at N-terminus of protein when mRNA is translated into protein (translation initiation codon).” Applicants did not indicate which bp of the XM\_007095 is considered to be the A of the ATG codon.

Applicants did not incorporate the two accession numbers by reference in the originally filed specification. Further, as shown in the attached GenBank revision histories for both of these sequences, the AL162497 sequence had 20 versions, and the XM\_007095 sequence had six. Applicants amended the specification to identify the version of sequence with GenBank Accession No. AL162497, but no language has been inserted indicating that this version is incorporated by reference as SEQ ID NO: 18. Further, Applicants did not identify the version of accession No. XM\_007095 or provide a sequence for it. The specification identified the positions of the polymorphisms with respect to the first ATG codon of the sequence with accession No. XM\_007095. The amended claims refer to the position of the polymorphisms within SEQ ID NO: 18, which is much larger than the gene itself. Therefore, to arrive at these positions, one had to first determine the position of the first ATG codon of the sequence with accession No. XM\_007095

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(which position was not provided by Applicants at the time of filing) and then translate this position by aligning the sequence with accession No. XM\_007095 with SEQ ID NO: 18. However, given the fact that there were six versions of the sequence with accession No. XM\_007095 and the position of the ATG codon within the sequence with accession No. XM\_007095 was not identified in the original disclosure, the polymorphism positions are not unambiguously identified.

Therefore, Applicants did not provide an adequate written description of the invention.

14. No references were found teaching or suggesting claims 23, 25-28, 30 and 32-37, but they are rejected for reasons given above.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TERESA E. STRZELECKA whose telephone number is (571)272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Teresa E Strzelecka  
Primary Examiner  
Art Unit 1637

/Teresa E Strzelecka/  
Primary Examiner, Art Unit 1637  
August 16, 2009